Washington University in St. Louis

February 10, 2003

Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Mail Stop E-79
Atlanta, GA 30333

On behalf of Washington University in St. Louis, we are writing in response to the Centers for Disease Control and Prevention's solicitation for comments on 42 CFR Part 73, *Interim Final Rule, Possession, Use, and Transfer of Select Agents and Toxins* published in the Federal Register, Vol. 240, No. 67 on Friday, December 13, 2002. The requirements set forth in this Interim Final Rule are designed to implement provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

As an academic, research, and medical institution, we recognize our obligations and responsibilities as they pertain to public health in general and to terror response preparedness, more specifically. We have and will continue to contribute to these efforts. Some of these efforts relate to direct involvement in regional preparedness planning and to providing subject matter expertise and support to local, state and Federal agencies. These efforts are on-going. But it is also important to recognize that fundamental institutional missions include patient care, teaching and research in many areas of concern to the public health, including biodefense and emerging infectious disease research. It is in our collective best interest to promote and facilitate fulfillment of these missions.

We acknowledge and respect the efforts of the DHHS and the USDA to, through this regulation, "provide protection against the effects of misuse of select agents and toxins" on the basis that they "have the potential to pose a severe threat to public health and safety." However, many in the research community have expressed concern about the process through which "select agent" lists have been established. We share this concern and encourage the agencies charged with oversight of 42 CFR Part 73 to continue in their efforts to adapt this Rule as our knowledge base continues to expand. It is imperative that our expenditure of resources be effective and efficient so that we can continue to improve our strategies directed toward this important public health issue.

The distinctive danger of true biological agents is in their ability to spread. One need only consider the recent spread of West Nile virus in the U.S. to appreciate the difference between the potential spread of a biological agent versus a strictly localized chemical or radiological event. The agents on the current lists are of concern, surely. Of equal or greater concern, however, are any number of easily imagined "engineered" organisms, especially viruses against which we have few vaccines and almost no therapy. Even benign viruses can be engineered into virulent forms. While we may not necessarily understand what specific modifications are needed to effect such a change in virulence (after all, the nature of biomedical research is to uncover such knowledge), we do need to develop a rational plan and processes to deal with this fundamental and unique feature of biological agents. Select agent lists will, by their very nature, become outdated and alone will not provide the public health protection we seek.

We encourage the U.S. Government to continue in its efforts to orchestrate the rich resources available collectively in its many agencies. For example, we encourage the continued coordination of efforts of oversight agencies such as the DHHS/CDC, DHHS/NIH and the USDA/APHIS, to name but three. We encourage the development of programs designed to augment the capabilities of local institutions to monitor the research activities they sponsor through comprehensive risk assessment (for example through the continued development of Institutional Biosafety Committees) and to better educate their staff about issues related to both safety and security.

We believe it is imperative that the Final Select Agent Transfer Rule satisfies two critical requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which are: (1) the Secretary provide for the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes; and (2) the safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin be commensurate with the risk such agent or toxin poses to public health and safety.

To this end, we support the comments and recommendations for 42 CFR Part 73 submitted by the Howard Hughes Medical Institute (HHMI) on January 21, 2003. We have attached a copy of the HHMI "Comments on 42 CFR Part 73" for your reference.

The basis for our support and endorsement is that the recommendations will ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes and will make the safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin risk-based. As stated above, these provisions are requirements of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Generally, the adoption of the recommendations of the HHMI will lessen the administrative burden of the Final Rule, allow for an effective performance-based security plan, and ensure the relevance of the Final Rule to the biomedical research environment.

We appreciate the opportunity to comment on the Interim Final Rule.

Sincerely,

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